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No. 01-660

IN THE

Supreme Court of the United States

ELI LILLY & COMPANY,
Petitioner,

v.

BARR LABORATORIES, INC., APOTEX INC., and BERNARD C. SHERMAN, GENEVA PHARMACEUTICALS, INC., and INTERPHARM, INC.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

MOTION FOR LEAVE TO FILE BRIEF *AMICUS CURIAE* AND BRIEF *AMICUS CURIAE* OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF CERTIORARI

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Pursuant to this Court's Rule 37.2, Intellectual Property Owners Association (IPO) respectfully moves for leave to file the attached brief *amicus curiae* in this case. The consent of the petitioner has been obtained. The consent of the respondent Barr Laboratories, Inc. was requested but refused.

Amicus IPO is a national organization that represents the owners of intellectual property in the United States. IPO's members include businesses and individuals who own or are interested in intellectual property rights. IPO regularly represents the interests of its member before Congress, the U.S. Patent and Trademark Office, and federal courts. The

association adheres to a policy of submitting *amicus* briefs only on significant issues affecting the owners of intellectual property rights.

IPO and its members have a substantial interest in the questions presented by the petition in this case. IPO members receive about 30 percent of patents granted by the U.S. Patent and Trademark Office to U.S. nationals. They may own many patents for basic inventions that were filed before but granted after patents for improvements in the basic invention.

In filing this brief, IPO seeks to bring to the Court's attention arguments and viewpoints in addition to those expressed in the petition for writ of certiorari. For example, IPO's brief points out that the Federal Circuit decision not only will harm owners of basic patents that were available as prior art with respect to improvement patents, as in the Lilly case, but also will harm owners of basic patents that were not available as prior art. IPO's brief expressly supports the doctrine of prosecution laches, citing *Webster Electric Co. v. Splitdorf Electrical Co.*, 264 U.S. 463 (1924). In summary, IPO's brief provides the Court with the perspective of a national association having members in all major industries and fields of technology, and the perspective of parties concerned about the effects on the patent system beyond the present case.

Respectfully submitted,

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INTEREST OF *AMICUS CURIAE*

Amicus Curiae Intellectual Property Owners Association (IPO), a tax-exempt association, is a national organization founded in 1972 to represent the owners of intellectual property in the United States.[1] IPO's members currently

[1] Pursuant to this Court's Rule 37.6, *amicus* represents that this brief was not authored in whole or in part by counsel for any party. Petitioner, an IPO member, made no monetary contribution to the preparation or submission of this brief beyond normal membership dues payments. No other person or entity made a monetary contribution other than IPO, its members, or its counsel.

include about 100 large and mid-sized companies and 250 small businesses, law firms, inventors, authors, executives and attorneys who own or are interested in patents and other forms of intellectual property in any industry or field of technology. IPO members receive about 30 percent of patents issued by the U. S. Patent and Trademark Office to U. S. nationals. IPO regularly represents the interests of its members before Congress and the U.S. Patent and Trademark Office, and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law.

IPO expressly declines to take any position on whether there is a factual basis for finding Lilly's claims to be invalid or unenforceable. IPO is concerned with the interests of all of its members in all industries and all fields of technology. IPO believes that the Federal Circuit misapprehended the law, and that the precedents established by the Federal Circuit's opinion, if it is not vacated or modified, will adversely affect existing and future patent rights of a large number of IPO members.

In this brief IPO explains misapprehensions of law that could affect the outcome of this and future cases. IPO believes its brief will be helpful to the Court in considering Lilly's petition for writ of certiorari. The filing of this brief was approved by the IPO Board of Directors, the members of which are listed in the Appendix.[2]

INTRODUCTION

The case concerns the validity of certain claims within a family of patents issued to Lilly relating to pharmaceutical compounds and methods of use of pharmaceutical compounds including fluoxetine hydrochloride, the active ingredient in Prozac®. The Federal Circuit concluded that

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[2] Eli Lilly & Co., which is represented on the Board, did not vote on whether to file the brief.

claim 7 of Lilly's '549 Molloy patent is invalid for so-called obviousness-type double patenting in view of claim 1 of Lilly's '213 Stark patent.

The '549 Molloy patent is a basic patent ("the basic patent") that relates to blocking the uptake of serotonin in an animal's brain neurons though the administration of Prozac®. The '213 Stark patent is an improvement patent ("the improvement patent") for the use of Prozac® to treat anxiety.

The basic patent, which was "first in, last out," was first filed for in a parent application on January 10, 1974, and was issued on December 2, 1986. The improvement patent was filed for on April 8, 1983 and issued on May 20, 1986, 7 months before the basic patent. The Federal Circuit determined that claim 7 in the *basic* patent was obvious in view of the earlier-issued *improvement* patent, and therefore, the *basic* patent is invalid for obviousness-type double patenting.

SUMMARY OF ARGUMENT

When a basic patent is filed before but issued after an improvement patent, the order of issuance is disregarded and the later-issuing basic patent is upheld if the improvement patent is not obvious in light of the basic patent. The Federal Circuit has misapprehended this rule of law, which applies in the absence of inexcusable delay. A patent owner should not be penalized for late issuance of a basic patent unless there was prosecution laches. The Federal Circuit decision will discourage inventors from applying for basic and improvement patents. The Federal Circuit also has misapprehended the law governing disclaimers of the terminal portion of a patent.

ARGUMENT

I. THE FEDERAL CIRCUIT MISAPPREHENDED THE LAW OF OBVIOUSNESS-TYPE DOUBLE PATENTING AS IT RELATES TO A BASIC PATENT FILED BEFORE BUT GRANTED AFTER AN IMPROVEMENT PATENT.

In holding that Lilly's basic patent is invalid for obviousness-type double patenting, the Federal Circuit has rendered a decision that is directly in conflict with the established rule, which is:

> When a basic patent is filed before but issued after an improvement patent, the order of issuance is disregarded and the later-issuing basic patent is upheld if the improvement patent is not obvious in light of the basic patent.

See 3 D. Chisum, *Patents*, § 9.03 [2][c] (2001) and precedents cited therein. The rule applies when the basic invention was available as prior art against the improvement invention and when it was not.[3] From the leading case of *Thomson-Houston Electric Co. v. Ohio Brass*[4] in 1897 until the Federal Circuit decision of May 30, 2001, we are unaware of any court invalidating an earlier-filed but later-issued basic patent for double patenting when the improvement patent was not obvious in light of the basic patent, in the absence of inexcusable delay.

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[3] In the present case the basic patent was available as prior art under 35 U.S.C. § 102(b) and § 103 with respect to the improvement patent because Lilly was granted an earlier patent on an application having the same disclosure as the basic patent. The precedent established by the Federal Circuit's decision, however, also will harm owners of basic patents that were not available as § 102(b) and § 103 prior art.

[4] 80 F. 712 (6th Cir. 1897) (William Howard Taft, J.)

The circumstances of the present case are dramatically different from those of *In re Berg*,[5] relied on by the Federal Circuit, where the basic and improvement applications were filed on the same day and the inventions were made "at nearly the same time" and could have been included in the same application. Lilly could not have included the basic and improvement inventions in the same application because the applications had no inventors in common and the inventions were not made at the same time. The application for the improvement patent was filed 9 years after the application for the basic patent.

The Federal Circuit's rule of invalidating the earlier-filed but later-issued basic patent if it is obvious in light of the improvement patent, in the words of Judge William Howard Taft in the *Ohio Brass* opinion, "would be a hard one; and . . . we should be inclined, if possible, to avoid declaring it to exist."[6] Claims for a basic invention always or almost always will be obvious in light of the improvement invention.

The opinion below failed to identify delay in prosecuting Lilly's basic patent that would be unreasonable or unjustifiable.[7] As observed by Judge Taft in *Ohio Brass*, ". . . the course of an application for a generic or broad invention may legitimately take longer in its course through the patent office than a comparatively unimportant improvement on that invention."[8] Footnote 7 of the opinion below adopts a nearly impossible-to-meet standard—that the U.S. Patent & Trademark Office must have been "solely" responsible for the delay—citing an expert who said "the claim could have been presented earlier." A claim granted

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[5] 140 F. 3d 1428, 46 USPQ 2d 1226 (Fed. Cir. 1998).

[6] 80 F. at 724.

[7] IPO has no position on whether delay in fact occurred that was unreasonable or unjustifiable.

[8] 80 F at 724.

in a basic patent generally could have been presented earlier. Moreover, it is very difficult for companies with significant patent portfolios to keep track of the status of basic and improvement patent applications in the Patent and Trademark Office. A patent owner should not be penalized for late issuance of a basic patent unless there was prosecution laches.[9]

II. THE FEDERAL CIRCUIT'S DECISION WILL DISCOURAGE INVENTORS FROM APPLYING FOR BASIC AND IMPROVEMENT PATENTS

The decision below establishes a precedent harmful to the patent system and the members of IPO. It denies innovators the full patent life to which they are entitled for their basic patents. The decision penalizes the basic innovator, who is the person most likely to make improvements in the basic invention but who now will be deterred from filing for patents on improvements. The prospect of losing patent term will discourage innovators from using the patent system and will weaken the patent system's incentives for innovation, investment and, commercialization.

The unfairness of the Federal Circuit's decision is highlighted by the fact that the full term of the basic patent would be available if the improvement patent were owned by anyone other than Lilly. Judge Taft's analysis in *Ohio Brass* was as follows:

> According to the argument of counsel, the patentees of the earlier improvement patent and the later main patent being the same person, the main patent is void. Let us suppose that they were different persons, but that, by

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[9] Cf. Webster Electric Co. v. Splitdorf Electrical Co. 264 U.S. 463 (1924); Brief of *Amicus Curiae* Intellectual Property Owners Association, *Symbol Technologies Inc. v. Lemelson Foundation, Limited Partnership* 00-1583 (Fed. Cir. 2000).

> mean assignments, the two patents became the property of one person; the effect upon the public use of the improvement patent is exactly the same as if the new owner had been the inventor and patentee of both. Does the unity of title avoid [sic: void] the main patent, which was valid before? It must be so if the argument of counsel for defendant on his behalf is to be followed, for the effect of the unity of title is "to extend the monopoly" of the earlier improvement patent in the sense in which the counsel uses that phrase. To our minds, this conclusion is reductio ad absurdum.[10]

III. THE FEDERAL CIRCUIT MISAPPREHENDED THE LAW GOVERNING DISCLAIMERS OF THE TERMINAL PORTION OF A PATENT TO OVERCOME AN OBVIOUS-TYPE DOUBLE PATENTING REJECTION.

The opinion below has created new law governing the use of a terminal disclaimer to overcome an obviousness-type double patenting rejection. Footnote 5 in the opinion states:

> A patent owner cannot avoid double patenting by disclaiming the earlier patent. Further, because Lilly disclaimed the '213 patent, it cannot now terminally disclaim the '549 patent to expire at the time the '213 patent would have expired had it not been disclaimed. . . .

We are aware of no precedent or rationale for a rule that a first-issued patent must still be in effect in order for the terminal portion of a second patent to be disclaimed. The Federal Circuit cites no authority for such a rule, and 35 U.S.C. § 253 provides no support. The opinion could open the door to arguments that no opportunity to file a terminal disclaimer is available in various circumstances. For example,

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[10] 80 F. at 727.

would a terminal disclaimer be available to overcome a double patenting rejection against a second patent after the first patent had lapsed for failure to pay a maintenance fee? Would a terminal disclaimer be available to overcome a double patenting rejection if the first patent had been declared invalid for reasons not affecting the second patent? IPO is concerned that the Federal Circuit's decision will create confusion in the law to the detriment of its members.

CONCLUSION

IPO believes the Federal Circuit misapprehended well-established precedent regarding obviousness-type double patenting. Accordingly, IPO urges this Court to grant the Petition for Writ of Certiorari.

Respectfully submitted,

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